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14. ABSTRACT

We have completed all the milestones for the study.

15. SUBJECT TERMS

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Introduction:

For younger men (<65 years of age) with high risk locally advanced (>stage 2C), active treatment with surgery or radiotherapy appears to improve disease-free and overall survival as compared to active surveillance (no active treatment). Minority men are less likely to receive active treatment but the reasons for this haven't been evaluated in younger men. Since black men with prostate cancer are younger at diagnosis, more likely to have poorly differentiated tumors, less likely to receive active treatment and more likely than white men to die of prostate cancer, it is possible that the quality of prostate cancer care delivered may be contributing to the racial disparity in mortality. While it is clear that physician recommendation and physician specialty affects the type of prostate cancer treatment recommended and ultimately received, little is known about racial differences in which treatments are offered to minority vs nonminority men and why. Nor are there data explaining younger minority men's lower rates of active treatment in circumstances when active surveillance does not achieve the same benefits of active treatment. This proposal seeks to determine whether the quality of care received by minority men with locally advanced prostate cancer differs from the care received by white men controlling for comorbidity, age and insurance. We are looking at reasons for the treatment choices minority men make including their experiences, their physicians' recommendations, beliefs about the prostate cancer, its treatment and consequences and assess racial differences in beliefs and potential causes of poorer quality care; and, are exploring urologists', radiation oncologists' and medical oncologists' perceptions of their decision-making and referrals among men with locally advanced prostate cancer.

Body:

During the 4 years of the project, we accomplished all the milestones as indicated in our scope of work. In the first year, we: 1) determined quality measures for prostate cancer treatment; 2) prepared the chart abstraction tool; 3) identified subjects for medical chart abstraction; 4) began abstracting medical records and data analysis; and 5) worked on developing the focus group guide. During the second year, we: 1) continued abstracting medical records; 2) completed the focus group guide; 3) continued data entry and analysis of chart abstraction data; and 4) designed the physician interview guide. During the third year, we: 1) continued abstracting records at Mount Sinai; 2) prepared IRB paperwork at Harlem Hospital; 3) Worked out patient identification at Harlem Hospital, 4) began conducting physician interviews, and 5) began identifying patients for focus groups at Mount Sinai. During the last year of the project, we:1) completed chart abstraction at both hospitals and identified underuse; 2) identified and attempted to recruit underuse patients for focus groups; 3) identified and recruited treated patients to focus groups (targeting patients with prolonged times between diagnosis and treatment); 4) conducted and analyzed 4 patient focus groups & interview; 5) completed physician interviews at both hospitals and analyses of these; and 6) developed final manuscript on patient-physician decision-making and care received.

Task 1: Determine Quality Measures for Prostate Cancer Treatment

As described in our first year's progress report, we created a steering committee of experts in the areas of urology, radiation oncology, medical oncology, general internal medicine and oncologic health services research. In order to prepare for the steering committee meeting, we prepared a comprehensive literature review and presented a summary of its findings to the committee. The review enabled them to decide on the scope of quality indicators to be used and areas of treatment controversy to be described. The steering committee reviewed the literature and finalized the quality measures we then applied in this study. These measures were based on randomized controlled trials with medium to high levels of evidence showing treatment effectiveness on disease-free and overall survival. Please see chart below for list of articles reviewed.

Prostate Cancer Quality Care PUBMED Search Results

Rx Category	Articles	Limits†	Exclusionsº	Final
RP vs. WW	358	20	17	3
RP vs. RT	2275	30‡	29	1
RP ± adjuvant RT	3036	59	55	4
Adjuvant vs. salvage RT	214	143*	141	2
RP ± adjuvant ADT	176	7	6	1
RP ± neoadjuvant ADT	1589	52	50	2
ADT ± RT	1641	85	83	2
EBRT dose	4240	128	121	7
IMRT vs. 3D-CRT	548	400°	397	3
RT ± neoadjuvant ADT	1648	85+	80	5
RT ± adjuvant ADT	1648	85+	80	5
Brachytherapy BED	1449	882*	880	2
Pre/post-treatment assessment	130	82*	81	1
Cryoablation vs. EBRT	700	3	1	2

†Unless otherwise indicated, limits are 10 years; Randomized controlled trial; humans (male); English
º Articles that do not include our demographic (i.e. Gleason ≥7) or do not directly report on the given category and patient outcomes such as bPFS and PCSM are excluded
‡ Expanding search to include comparative studies from 1998 to present yielded two additional articles
* Limits are 10 years; Journal article; humans (male); English
° Limits are from 2001; Journal article; humans (male); English
+ a google scholar search yielded 2 additional articles

Task 2: Preparation for Medical Chart Abstraction

After our steering committee agreed upon the quality measures, we designed our chart abstraction tool to capture prostate cancer treatments recommended and received by men with a Gleason score of ≥7. In addition, we abstracted all medical records for clinical characteristics including comorbidity, 9-year Schonberg Prognostic Index, demographics, pathology, PSA level, smoking status and descriptors of functional status. The chart abstractor was then trained on the use of the electronic medical records and location where to find treatment data as per the protocol.

Task 3: Subject Identification for Medical Chart Abstraction

In order to identify patients at Mount Sinai, we met with members of the Data Warehouse (clinical research data repository for the institution) and members of the IT in the Department of Pathology to develop the program that would compile the list of potentially eligible patients with a Gleason score >7. Pathology does not routinely collect and report race and not all prostate cancer patients are identified in the Data Warehouse. After merging the 2 data sources, there were 1991 patients with Gleason 7-10 of whom 1306 were white and 350 were black. Based on prior tumor registry data, we had anticipated a higher number of black men (~100/yr) and planned to abstract 870 cases. Given the realities of the sample, we revisited the power calculations: assumed an underuse rate of 6% in blacks and 1.2% in whites (as per SEER Medicare - Shavers,

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et al, 2004), we determined that using all 350 black and 350 white men would give 80% power to detect a racial difference in treatment. Of course, this assumed the underuse rate was similar in younger populations as to Medicare populations; thus we aimed to abstract 870 cases to ensure power to identify a racial difference in quality of cancer care. The 350 white men were randomly selected from groups matched by Gleason score and age to the black men.

In order to make the study more generalizable we requested to add Harlem Hospital, a municipal hospital serving predominantly minority patients, to the study. In this second year, we worked on the IRB paperwork for Harlem Hospital Center to abstract the remaining 170 records at that site, a critical piece as Harlem Hospital serves a poorer patient population.

We encountered numerous obstacles in getting the study started at Harlem Hospital in our third year. IRB approval was obtained from the IRB of record however HHC approval (internal organizational approval) had internal signoff delays and was finally approved after several months. Despite initial buy-in by the Principal Investigator and IRB & organizational approval, there was a delay with allowing study chart abstractors review the medical records. Despite these challenges, we met with Pathology, IT and the tumor registry to identify white, and black men with a Gleason score ≥ 7 applying the same criteria used with the Mount Sinai sample. The Pathology Department did not have a searchable electronic system which allowed for patient identification; therefore, we worked with IT and the Tumor Registry to be able to identify the sample.

Task 4: <u>Abstraction of Medical Records</u>

In our second year, we abstracted 623 charts of men with a Gleason sum of 7-10 at Mount Sinai, 539 were eligible for inclusion: 34 had prior h/o cancer; 30 had metastatic cancer; 20 were missing pathological staging and had PSA <10. Given that treatment records for the various clinics are stored in separate locations it took us some time to collect RT and ADT information as these were located in paper-charts outside the EMR system. As some men received their post-surgical or RT care outside of Mount Sinai Hospital, we also had to reach out to numerous office practices to obtain missing treatment information.

In our third year, we encountered some unexpected challenges with chart abstraction at Mount Sinai as we found key critical elements missing from one particular surgeon's charts whose paper charts were not available on EMR. After several months, we obtained permission to review the paper charts and we re-reviewed 300 charts in order to obtain the missing data. Despite the unexpected delay we completed the chart review of Mount Sinai and Harlem patients. We abstracted a total of 686 Mount Sinai and 148 Harlem Hospital charts.
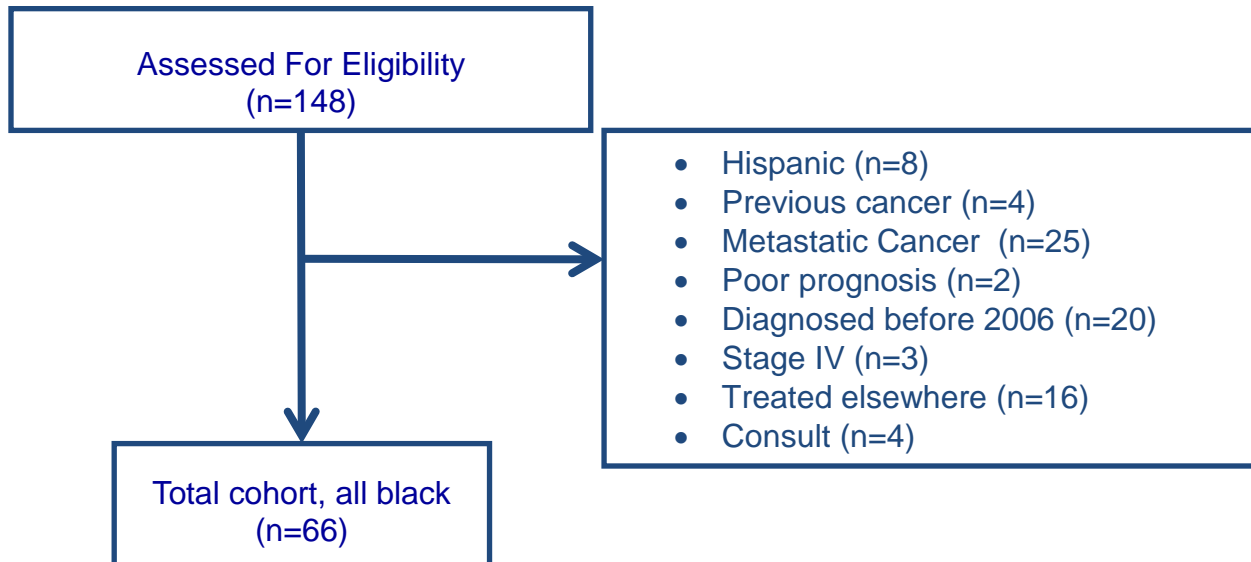
Task 5: <u>Development of Focus Group Guide</u>

Drs. McAlearney and Lin, our qualitative experts, along with Dr. Bickell worked to develop the Focus Group Moderator Guide in the second year. These focus groups were to be conducted among men with and without active treatment to explore their beliefs about prostate cancer, its treatment, physician recommendations and medical mistrust.

Task 6: <u>Data Entry & Analysis of Chart Abstraction Data</u>

Data was entered from the paper records into an access database. The data was then cleaned and prepared for analysis. Patient race was based on administrative reporting of race. All black patients were retained in the study (n=359). Gleason score-matched white patients within 10-year age groups (<60, 60-69, 70-79, 80+) were selected at random (n=282), providing a final yield of 641 patients. D'Amico intermediate and high-risk prostate cancer cases were included as these were considered most likely to be clinically significant; low-risk cancer cases were excluded for this analysis.

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┌─────────────────────────────────┐
│   Assessed For Eligibility      │
│          (n=148)                │
└─────────────────────────────────┘
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- Hispanic (n=8)
- Previous cancer (n=4)
- Metastatic Cancer (n=25)
- Poor prognosis (n=2)
- Diagnosed before 2006 (n=20)
- Stage IV (n=3)
- Treated elsewhere (n=16)
- Consult (n=4)

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┌─────────────────────────────────┐
│   Total cohort, all black       │
│          (n=66)                 │
└─────────────────────────────────┘
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Academic Center Patients:

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┌─────────────────────────────────────────┐
│   Assessed For Eligibility (n=686)       │
│                                          │
└─────────────────────────────────────────┘
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- Previous Cancer (n=52)
- Metastatic Disease (n=36)
- Poor Prognosis (n=7)
- Diagnosed before 2006 (n=1)
- Stage IV (n=2)
- Consults Only (n=13)

Total ineligible (n=111)

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┌─────────────────────────────────┐
│   Total Cohort (n=575)          │
│                                 │
└─────────────────────────────────┘
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┌──────────────────────┐     ┌──────────────────────┐
│   Black/Hispanic     │     │        White         │
│   (n=293; 51%)       │     │   (n=282; 49%)       │
└──────────────────────┘     └──────────────────────┘
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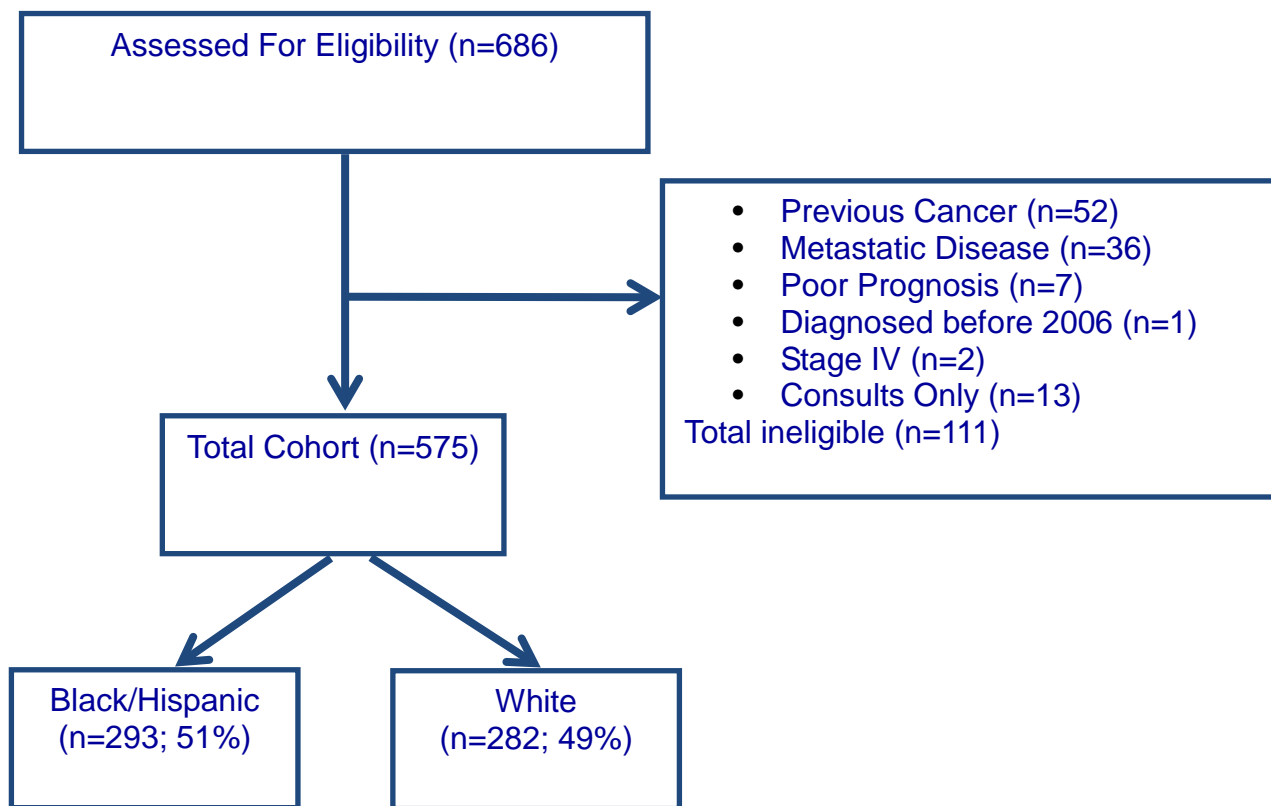
Types of Treatment Received & Underuse of Definitive Treatment

Primary treatment was categorized into surgery (open, laparoscopic or robotic-assisted radical prostatectomy), radiotherapy (External Beam Radiation Therapy (EBRT) &/or brachytherapy), cryotherapy or androgen deprivation therapy (ADT). Underuse was defined as: treatment with ADT monotherapy for cases treated after the Widmark 2009 seminal publication, or no radical prostatectomy, no radiotherapy (EBRT or brachytherapy) or no cryotherapy in men with intermediate or high risk prostate cancers.

We used bivariate t-tests and chi-square tests to compare patient characteristics between the two racial groups. We used multivariable conditional logistic regression models to determine which clinical and demographic factors most affected the likelihood of underuse in this matched sample.

Task 7: Recruitment and Conduct of Focus Groups

In our 3rd year, we worked with our data analyst to identify a sample of Mount Sinai patients for focus groups. We took a random sample of patients who received treatment for their prostate cancer and matched them based on race, gleason, and age.

Originally, we intended to conduct ~8 patient focus groups, at least 4 black, and 4 white. We aimed to include minority men without active treatment, and those with active treatment. We planned to recruit men who experienced "poorer" quality of care. The low numbers with underuse made it impossible to reach the numbers we'd anticipated. We tried numerous times to contact the 25 underuse patients – unsuccessfully. Most had moved and were unreachable or died. To identify patients for the focus groups to explore patient decision-making, we searched for those patients with longer times between diagnosis and treatment with the goal of finding men who may have encountered significant barriers to care.

Task 8: Design of Physician Interview

In our second year, Drs. McAlearney and Bickell, worked to develop Physician Interview Guide. The physician interview guide served to explore physicians' general approach to treating prostate cancer patients and then specific reasons for treatments given to, withheld or delayed for specific patients.

Task 9: Analysis of Focus Groups

Analysis of focus groups used both deductive and inductive approaches. Deductively, an initial code list was created based on a review of the literature around treatment decision-making, and followed the Health Belief Model (HBM). The HBM provides an established framework that can be useful in understanding factors associated with individual health behavior, such as decision making. This model has also previously been applied to understanding prostate cancer Treatment Decision Making (TDM). Coding of the focus group transcripts was also inductive, allowing the development of new codes based on patterns that emerged from the data. Throughout the coding and analysis process, the coding dictionary was refined as emergent codes were added. Each focus group was coded by two experienced researchers to ensure consistency in coding, and agreement about coding decisions and emergent themes. Several themes emerged regarding cues to action and key elements of the Health Belief Model (HBM). These include:

PATIENT TREATMENT DECISION FACTORS:

External Factors:

      a. Peer cues to action: friends, relatives, celebrities (Mayor Guiliani)
      b. Family considerations: life insurance policy
      c. Financial considerations: cost, insurance
          i. Before even the cost of the treatment, money enables you to seek out more opinions – gives you more choice

Social Factors:

      d. Motivation: feeling like they should do something about their disease given what has been observed in friends and family w/ PC
      e. Lack of Self-efficacy: feeling limited in their choices due to disease state, or from peer experiences. Feeling like treatments were all about equal, so prefer surgery to have clear pathology report.

f. Fear and Anxiety: fear over having 'cancer' and desire to just get rid of 'cancer' by any means necessary.
g. Variable Decision Styles: some patients had little knowledge and preferred it that way so as to prevent them from making poor treatment choices; others did independent research and reached out to lots of friends/ family and made their decision regardless of physician recommendation.

Knowledge Factors:

h. Patient-Provider Relationships: patients expressed significant trust and confidence in their physician, and felt that they were explained the risks/ benefits of different treatments and side effects. One patient expressed trust in their physician, but concern that a different physician could actually be doing surgery when he was under anesthesia. This seems to be more distrust in the medical system.
i. Perceived Risks/ Benefits: patients often did their own research to evaluate the risks/ benefits. Overall, patients tended to base treatment decision on the likelihood of side effects.
j. Lack of Knowledge: Despite saying that they received thorough consultation, several patients expressed feeling like they did not fully understand the side effects, and that this actually *helped* them make a better treatment decision. If they had known about the side effects (particularly impotence, but also incontinence), they would have decided not to receive treatment and would have died.

Clinical Factors:

k. Side-effects: the perceived likelihood based on clinical factors (age, comorbidities, etc…) of being impotent or incontinent was a major factor influencing treatment decisions.
l. Health literacy (varied): judging from the language patients used to discuss their disease, some patients had very high health literacy, while others showed confusion over key terminology (e.g. impotence vs. incontinence).

Task 10: Physician Interviews

We conducted semi-structured interviews with 15 of the 17 physicians who treated 22 of the 25 underuse patients: 10 urologists, 2 medical oncologists, 3 radiation oncologists with an average of 20.5 yrs in practice; 13% practiced at a municipal hospital, 40% practiced at an academic medical center, and 47% practiced in a private office practice affiliated with the academic medical center. Two physicians caring for 3 patients were unreachable.

Analyses of physician interviews were conducted using the same approach as with the focus groups. Deductive and inductive approaches were used based on review of transcribed interviews. The themes that arose include:

PROVIDER TREATMENT DECISION FACTORS:

1) External Factors:
    a. Peer cues to action: recognize the power of friends, relatives, celebrities (Mayor Guiliani) experience
    b. Spouse: very cognizant of the role the spouse plays in determining treatment. Spouses are often less concerned with side effects and more concerned with survival.
    c. Insurance (variable): some say it is irrelevant, that everything is covered.   Others say sometimes the insurer can reject the treatment choice, but that often other options exist to help with cost. Overall, this issue was more prevalent at the municipal hospital.
    d. Medical System: current reimbursement environment incentivizes treatment, even when it may not really be worth it. Also, cannot spend the time they want with patients.

e. Legal Concerns: the medico-legal environment influences treatment and testing decisions – have to test.

2) Social Factors:
   a. Motivation: physicians can be motivated by personal financial gain, such as using expensive machines they have purchased (e.g. IMRT), or doing treatments they will receive greater reimbursement for.
   b. Variable Decision Styles: patients generally have prior knowledge, albeit with some misconceptions, and often already have mind made up about what treatment they want. Physicians always recommend seeking other opinions.
   c. Fear and Anxiety: patients often very scared, and this can lead to making aggressive (and not recommended) treatment decisions.

3) Knowledge Factors:
   a. Patient-Provider Relationships: felt that building a trusting relationship was critical. To build this, they often incorporated the spouse in consultation.
   b. Perceived Risks/ Benefits: physicians viewed there role as to provide consult, not to decide for the patient. They provided all risks/ benefits of treatments/ side effects. However, often felt that spouses and peers were greater influences then the information they provide.   Felt that it was better to provide all info upfront rather than be accused of not doing it after the fact.
   c. Decision Aids: based on past experiences, providers did not rely on handouts or material to distribute to patients because they felt that patients did not value these. Similarly, previously established peer education groups did not prove useful.

4) Clinical Factors:
   a. Comorbidities: patient comorbidities (e.g. chronic diseases; other cancers; previous prostate cancer treatment) influenced treatment options.
   b. Risk profile: patient age, race, family history were all important considerations.

Task 11: Final Analyses and Report Writing

In the last year of our project, we worked on completing our data analysis and prepared our study findings for publication. Our final sample included 641 men (359 Black; 282 white) with locally advanced prostate cancer.

Patient Characteristics: At the academic center, 575 men and 66 at the municipal hospital were included (See CONSORT Figure 1). Of the 641 men with clinically significant prostate cancer, 56% were black and 84% had high risk cancer by D'Amico criteria (see table below). The average age of our study population was 60.5 (± 8.7) years; there was no racial difference in age. Black men were more likely than white men to have multiple comorbidities (32% vs 11%; p<.0001), intermediate D'Amico cancer risk (19% vs 11%; p<.0001), more had low 9 year life expectancy (53% vs 40%: p<.0001) and less had commercial insurance (66% vs 88%; p<.0001).

Underuse and Treatments Received: Initially, we identified 53 cases of underuse based on chart abstraction data. After interviewing physicians about the underuse cases, 28 were reclassified [13 treated elsewhere, 5 metastatic at presentation, 4 with poor prognosis due to other condition, 4 treated with ADT monotherapy prior to 2009 seminal article, 2 clinical exceptions, e.g., advanced age]. Only 25 men with clinically significant prostate cancer experienced underuse; 23 were black (92%). Sixteen (64%) were treated at a safety-net hospital and 9 at the academic center. While underuse was low overall (4%), black men were significantly more likely than white men to experience underuse (6% vs. 1%; p<0.0001). Surgery was the predominant primary treatment, but white men were much more likely than black men to receive surgery (91% vs. 69% respectively; p<.0001). Radiation therapy was more prevalent among black than white men (21% vs. 7% respectively; p<.0001).

Multivariate Model - Factors Predicting Underuse: Multivariate conditional logistic model found that underuse was not associated with age (OR=0.6; 95% CI: 0.2-1.8), low life expectancy (OR=1.3; 95%CI: 0.4-3.9), comorbidity (OR=1.6; 95%CI: 0.6-4.1), or black race (OR=3.9; 95%CI: 0.8-36.5). Rather, commercial insurance

(OR=0.09; 95%CI: 0.03-0.30) and intermediate D'Amico cancer risk (OR=3.6; 95%CI: 1.3-9.8) were significant predictors of underuse of definitive treatment. A race-insurance interaction was not significant and not included in the final model.

We also found that mortality risk did not affect treatment rates among older or younger men. It did, however, affect the type of treatments received by older men. Low mortality risk older men were significantly more likely than higher mortality risk older men to undergo surgery (85% vs 49%; p<.0001).

Patient Characteristics and Treatment Received by Race

	Total (N=641)	Black (N=359, 56%)	White (N=282, 44%)	p-value
Age (years, means ± SD)	60.5 ± 8.7	60.9 ± 9.2	60.0 ± 8.0	0.2
Comorbidity (>0)	145 (23%)	114 (32%)	31 (11%)	<.0001
Diabetic	90 (14%)	74 (21%)	16 (6%)	<.0001
Obese†	148 (28%)	84 (30%)	64 (25%)	0.2
PSA prior to diagnosis†	9.3 ± 13.6	11.6 ± 17.5	6.4 ± 4.3	<.0001
Gleason Sum				0.1440
7	564 (88%)	309 (86%)	255 (90%)	
8	34 (5%)	23 (6%)	11 (4%)	
9+	43 (7%)	27 (8%)	16 (6%)	
D'Amico				0.009
Intermediate	100 (16%)	68 (19%)	32 (11%)	
High	547 (84%)	297 (81%)	250 (88%)	
Stage†				0.0244
IIA	69 (12%)	41 (14%)	28 (10%)	
IIB	347 (62%)	185 (64%)	162 (59%)	
III	147 (26%)	62 (22%)	85 (31%)	
Smoking†	76 (13%)	47 (15%)	29 (11%)	0.2
Insurance				<.0001
3rd party commercial	485 (76%)	237 (66%)	248 (88%)	
Medicaid	50 (8%)	49 (14%)	1 (0.4%)	
Medicare	56 (9%)	40 (11%)	16 (6%)	
Self-pay	23 (4%)	13 (4%)	10 (4%)	
Unknown	27 (4%)	20 (6%)	7 (2%)	
Low 9-year life expectancy mortality risk (<0.74)	305 (48%)	191 (53%)	114 (40%)	0.001
Quality of life Assessment	490 (76%)	278 (78%)	211 (75%)	0.4
Primary Treatments Received:				<.0001
Radical Prostatectomy	505 (79%)	247 (69%)	258 (91%)	
Cryoblation	7 (1%)	6 (2%)	1 (0.4%)	
Brachytherapy	60 (9%)	42 (12%)	18 (6%)	
EBRT primary	34 (5%)	31 (9%)	3 (1%)	
ADT monotherapy	10 (2%)	10 (3%)	0	
Underuse definitive Rx	25 (4%)	23 (6%)	2 (1%)	<.0001

†Numbers may not add up because of missing data.

The vast majority of underuse patients had treatment recommended but it was not received. Via physician interviews we found that nearly ¾ of these cases were due to system failures, the remaining ¼ were due to patient refusal or financial barriers. Importantly, system failures occurred more often among black men. Of the system failures – cases in which treatment is recommended, not refused but does not ensue, nearly 40% continued receiving care at the hospital. These cases represent missed opportunities to redress racial disparities in cancer treatment. Interestingly, a small proportion of the system failures included men who were slated to undergo primary radiotherapy (EBRT) and were started on ADT. Interviews revealed that these men did not go on to receive the needed radiation. Rather, the urologists thought these patients were erroneously treated with ADT as metastatic patients and their primary treatment never occurred.

Underuse Category	Reason		N = 22
Treatment Recommended But Not Received 21 (95%)	Non-adherence	Financial Barriers	1 (4.5%)
		Patient Refusal	4 (18%)
	System Failure*	Lost to Follow Up	14 (64%)
		Lost within Treatment	2 (9%)
Non-Guideline Concordant Treatment Received 1 (5%)	Favorable Histology (small tumor), comorbidity or old age		1 (4.5%)

Focus Group Findings:
Using the domains of the HBM to frame the data, we found similarities and differences across sites in patient focus groups. Below we discuss this site comparison in greater, examining each of the four factors of this model in turn: external, social, knowledge, and clinical.

External Factors: For patients at the two hospitals, differences emerged in the discussion of external factors that influenced TDM, particularly around the issues of peer cues to action, and financial considerations. Patients at the resource-rich hospital discussed the impact of seeing family members, friends, and even celebrities, going through treatment (or lack of treatment), and how that experience motivated their treatment decisions.

Financial considerations were mentioned primarily as a barrier for patients at the resource-poor hospital. In contrast, at the resource-rich hospital, patients described having options and seeking out medical opinions from several doctors located in geographically distant locations. This availability of options, and traveling to seek other opinions was not mentioned among patients from the resource-poor hospital.

Social Factors: Social factors discussed by the patients at the two hospitals appeared more individually dependent rather than institutionally based, as similar themes were described by patients at both sites. Patients at the both hospitals described being motivated to seek treatment, often in order to avoid the experiences they had observed of relatives or friends that had prostate (or other) cancers. Patients at both hospitals discussed their information-seeking process, including their desire to have control over their treatment decisions. Alternatively, some patients at both hospitals were more passive in their information seeking approach, based on their view of the outcomes. Despite these differences in perceptions regarding control and their decision styles, patients from the resource-poor hospital also expressed fear and anxiety regarding treatment decisions, and these emotions were not noted by patients at the resource-rich hospital.

Knowledge Factors: Patients at both sites noted the importance of their relationship with their physician in the TDM process. At both sites, patients voiced significant trust and confidence in their physician, and felt that the physicians did a thorough job explaining the risks, benefits, and side-effects of each treatment. Patients felt that from both their physician, and through their own information seeking, they had sufficient information to make an informed decision regarding treatment modality. Overall, they felt that their choice of treatment depended more on their perceptions of side-effects, rather than the treatment itself because they felt that all treatments were equally beneficial.

Despite emphasizing trust, patient views at both hospitals were also inconsistent: at the resource-rich hospital they also expressed distrust in their physician and in the medical system in general. At the resource-poor hospital, in contrast, patients did not express distrust, but did comment that they believed they had not been told the complete story about treatment options. Several patients discussed that they did not know about the

two primary side-effects (impotence and incontinence), and had they known about these they would have not have elected to receive treatment, likely resulting in death.

Clinical Factors: For patients at both sites, the primary clinical factor that played into their TDM was their likelihood of experiencing side-effects, particularly impotence and incontinence. As patients discussed clinical factors, a differentiating factor that emerged was an apparent variation across the two sites in health literacy: while patients at the resource-rich hospital described their disease state in very technical language, those at the resource-poor hospital struggled with the meaning of key terms (e.g., impotence and incontinence).

Patient themes present at two hospitals.

	Resource Poor Hospital	Resource Rich Hospital
External Factors	*Peer Cues to Action*	*Peer Cues to Action*
	Limited Treatment Options	*Available Treatment Options*
	Cost as a Barrier	*Cost as a Motivator (e.g., to seek treatment elsewhere)*
Social Factors	*Control (Decision Style)*	*Control (Decision Style)*
	Self-Efficacy	*Self-Efficacy*
	Motivation	*Motivation*
	Fear & Anxiety	
Knowledge Factors	*Patient-Provider Relationship (Trust)*	*Patient-Provider Relationship (Trust)*
	Perceived Knowledge of Risks/ Benefits	*Perceived Knowledge of Risks/ Benefits*
	Lack of Knowledge as a Beneficial	*Lack of Trust*
Clinical Factors	*Side Effects*	*Side Effects*

Key Research Accomplishments:
- Completed chart abstraction
- Completed physician interviews
- Completed patient interviews and focus groups
- Completed data analysis of quality indicators
- Completing qualitative analyses of physician interviews
- Completing qualitative analyses of patient focus groups and interviews

Reportable Outcomes & Conclusion:
We found very low rates of underuse of locally advanced prostate cancer effective treatments. There was a racial disparity in underuse with 92% of underuse patients being black (p<0.0001). Surgery was the predominant primary treatment, but white men were much more likely than black men to receive surgery (91% vs. 69% respectively; p<.0001). Multivariate conditional logistic model found that underuse was not associated with age (OR=0.6; 95% CI: 0.2-1.8), low life expectancy (OR=1.3; 95%CI: 0.4-3.9), comorbidity (OR=1.6; 95%CI: 0.6-4.1), or black race (OR=3.9; 95%CI: 0.8-36.5). Rather, commercial insurance (OR=0.09; 95%CI: 0.03-0.30) and intermediate D'Amico cancer risk (OR=3.6; 95%CI: 1.3-9.8) were significant predictors of underuse of definitive treatment. Older men with good life expectancy are much more likely to be treated with surgery than those with poorer life expectance.

Qualitative interviews with urologists, radiation and medical oncologists, found the vast majority of underuse were due to system failures, cases in which the physician recommended treatment, the patient did not refuse, yet, care did not ensue. These appear to be potentially remediable and avoidable causes of underuse.

Physicians at different hospitals experience varying barriers to implement recommended cancer care. Patient and physicians do have overlapping cues to action and treatment decision-making but also differ in significant ways as to the factors that affect treatments received.

<u>Bibliography References</u>

<u>Presented Abstracts:</u>

Fei K, Veluswamy R, Franco R, Bickell NA. Are there Racial Disparities in Quality of Treatment for Locally Advanced Prostate Cancer? Poster Presentation. Academy Health Annual Meeting June 2014 & Society of General Internal Medicine Annual Meeting April 2014

Bickell NA, Hall S, Stock R, Fei K, Veluswamy R, Franco R, Oh W. Does Race Affect the Quality of Treatment for Intermediate and High risk Prostate Cancer? Online Publication. American Society for Clinical Oncology Annual Meeting 2014

Abramson S, Lin JJ, McAlearney AS, Fei K, Franco R, Bickell NA. Why Men Get or Don't Get Treated for Locally Advanced Prostate Cancer: Physicians' Perspectives. Poster Presentation. Society of General Internal Medicine Annual Meeting, American Society for Clinical Oncology Annual Meeting, Academy Health Annual Meeting June 2015

Supoyo S, Hall S, Stock R, Hoke GP, Oh W, Fei K, Franco R, Bickell NA. Treating Older Men With Locally Advanced Prostate Cancer – Is It Underuse Or Clinical Judgment? Poster Presentation. Society of General Internal Medicine Annual Meeting June 14, 2015 & American Geriatric Society Annual Meeting Dec 2014 (Presidential Student Poster)

Bickell NA, Abramson S, Walker D, Sova L, Lin JJ, Fei K, Franco R, McAlearney AS. Patient and clinician perspectives on treatment decision-making for African American men with prostate cancer. ASCO Quality Symposium 2016

<u>Manuscripts under review:</u>
Bickell NA, Abramson SR, Lin JJ, Hoke GP, Oh, W, Hall SJ, Stock R, Fei K, McAlearney AS. Racial Disparities in Clinically Significant Prostate Cancer Treatment. Where Do We Go from Here?

Fei K, Supoyo S, Franco R, Abramson S, Bickell NA. Treating Older Mend with Clinically Significant Prostate Cancer – Is it Ageism or Clinical Judgment?

<u>Personnel:</u>

<u>Principal Investigator</u>: Nina. A. Bickell MD., MPH
As Principal Investigator, Dr. Bickell planned and directed all activities of the research project including the design of all data collecting instruments including chart abstraction tool and physician interview surveys, recruited Steering Committee, developed moderator guide for focus groups, conducted physician interviews and patient focus groups, refined identification criteria from pathology to identify eligible subjects for chart abstraction, and analyzed the data along with Drs. Oh, McAlearney and Lin.

<u>Co-Investigator</u>: William Oh, MD
Dr. Oh worked along with Dr. Bickell in all activities of the research project including the design of the data collection instruments including chart abstraction tool, recruiting and directing the Steering Committee, refining pathology identification criteria to identify eligible subjects for chart abstraction, interpreting chart abstraction data and helping prepare findings for publication.

<u>Investigator</u>: Simon Hall, MD
As Investigator, Dr. Hall assisted Drs. Bickell and Oh with recruitment and conduct of Steering Committee, development of the chart abstraction tool, refined subject identification criteria for pathology, facilitated patient

participation in focus groups and assisted with interpretation of study findings for presentations and publications.

Investigator: Jenny J. Lin, MD
Dr. Lin worked alongside Dr. Bickell in the development of the moderator guide for the patient focus groups, conducted physician interviews as well as assisted Drs. Bickell and McAlearney with both focus group findings and physician interview analyses and interpretation.

Pathologist: Pamela Unger, MD
Dr. Unger provided the pathology reports that were used to identify eligible patients for chart abstraction and recruitment for focus groups as well as assisted the Steering Committee with state of the art evidence-based recommendations regarding pathology diagnostic and histological factors.

Data Analyst: Kezhen Fei, MS
Ms. Fei, assisted in assessing data progress, cleaning, and analyzed the results of the chart abstractions. She prepared and analyzed data for case identification for patient focus groups (those with prolonged delays in treatment receipt), presentations and publications.

Project Manager: Rebeca Franco, MPH
Ms. Franco assisted Dr. Bickell and Ms. Fei with data merging, cleaning, administration and oversight of all aspects of the project.

Data Abstractors: Sarah Abramson
Ms. Abramson helped gather prostate cancer treatment information for the study. In addition she assisted Drs. Bickell and Lin with the physician interviews and analyses. Source of funding: New York Academy of Medicine

Data Abstractors: Stephen Supoyo
Mr. Supoyo helped gather prostate cancer treatment information for the study. In addition, he assisted Dr. Bickell with arranging focus groups and interpreting findings. Source of funding: MSTAR

Subcontracts
Ohio State University
Co- Investigator: Ann Scheck McAlearney, Sc.D., M.S.
Dr. McAlearney contributed her expertise in qualitative methods, focus groups and individual interviews, and qualitative analysis of the project.

Harlem Hospital Center (subcontract through Health & Hospitals Corporation)
Co-Investigator: Gerald Hoke, MD
Dr. Hoke was responsible for helping to guide the proposal through the IRB and HIPAA processes at Harlem, assist with recruiting urologists to participate in physician interviews and facilitated the processes that enabled identification of cases through pathology and chart abstraction and recruitment of participants to focus groups and physician interview.

Supporting Data:
None.